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(71)(72) Applicant and Inventor: SOLEM, Jan, Otto [SE/SE]; Nordmannavägen 20, S-237 31 Bjärred (SE). (74) Agent: AWAPATENT AB; P.O. Box 5117, S-200 71 Malmö (SE).	Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: ANASTOMOTIC FITTING		
(57) Abstract		
<p>For connecting the end of a first blood vessel (6) to the side of a second blood vessel, which preferably has a greater diameter than the first blood vessel, use is made of a sleeve (11, 11') whose one end portion (12, 12') is expandable for the forming of an annular end flange (15, 15'). As a result, the first blood vessel (6), after being passed through the sleeve (11, 11') in the direction of the expandable end portion and folding back at least over the expandable end portion, is formable into a collar, both sides of which enclose the annular end flange inside the second blood vessel and internally surround an opening formed therein.</p>		

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ANASTOMOTIC FITTING

The present invention relates generally to the field of vascular surgery and, more specifically, to a connecting device for blood vessels, especially the aorta in bypass operations on the coronary vessels.

5 An increased flow resistance in the various coronary vessels can jeopardise the oxygen supply to the cardiac muscle. In some cases an expansion of the vascular lumen is possible. If the flow of blood in a vessel is completely or practically completely blocked, the only thing
10 to be done is to bypass the blocked portion to prevent an irreparable injury from arising. Such a bypass operation is usually effected by connecting a new vessel after the blocked point and connecting it to another blood vessel, for instance the aorta, which may give a sufficient flow
15 of blood to the blood vessel after the blocked point.

Such a bypass operation normally requires the use of a heart-lung machine, i.e. that the heart be temporarily stopped, since the bypass operation when connecting, for instance, the two vessels involved requires the heart to
20 be immovable. In consequence of the connecting technique employed and the use of the heart-lung machine, the operation will be relatively time-consuming and not without risk.

International Patent Application No. PCT/SE97/00804
25 discloses a branching device, which to a considerable extent facilitates the connection of the new vessel to the coronary vessel suffering from stenosis, but this branching device is not suited for connection of the new vessel to e.g. the aorta mainly owing to the difference
30 in size.

The object of the present invention therefore is to provide a simple and reliable connection of the new vessel to a blood vessel, for instance the aorta, which can give a sufficient flow of blood to the constricted blood

vessel via a branch after the constriction. Preferably it should also be possible to design the connection in a manner which makes it possible that the heart-lung machine need not be used. Most preferably it should be 5 possible to carry out the operation by applying endoscopy.

According to the invention, this object is achieved by the connecting device being given the features that appear from the accompanying claim 1. Preferred embodiments of the connecting device appear from the dependent 10 claims.

The inventive sleeve thus makes it possible to create a collar from the end of a first blood vessel. The collar can be made to extend around the inside of an 15 opening formed in the second blood vessel. As a result, a relatively large overlapping can be achieved in the connecting area between the first and the second blood vessel, which in turn permits a highly reliable connection of the two vessels.

20 In the preferred embodiment, use is made of a balloon for expanding the end portion of the sleeve and, thus, for forming the collar. More precisely, the balloon is equipped with an inlet tube, which can be passed through the sleeve, such that the balloon itself will be 25 positioned adjacent to the expandable end portion in order to accomplish, by inflation, the expansion thereof and at the same time also form the collar from the first blood vessel.

For fixing the position of the balloon during inflation thereof such that the resulting pressure acts 30 against the expandable end portion of the sleeve, the inlet tube of the balloon suitably is made of a substantially nonelastic material.

In the preferred embodiment of the inventive device, 35 the balloon besides has a nonelastic portion, which abuts on the inlet tube and in extended state has a shape corresponding to the desired shape of the annular end flange

and, thus, the collar. This ensures still more that the expandable end portion of the sleeve is affected in the correct manner for the shape of the annular flange to be correct.

5 According to the invention, a locking ring is advantageously used to fix the two blood vessels. The locking ring can receive the sleeve and be displaced along this to a position adjacent to the annular flange, mutually overlapping portions of the first and the second vessel
10 being positioned therebetween. With the aid of suitable fixing means, e.g. pins with barbs, which can be integrated with the locking ring and directed axially relative to the sleeve, the first and the second blood vessel portions, which overlap each other, can be interconnected
15 in a simple and reliable manner around the opening formed in the second blood vessel.

The entire sleeve but preferably only its expandable end portion can advantageously be made of a net-like flexible material, but the end portion can alternatively
20 be formed by making a plurality of axial slots from the one end of the sleeve.

The invention will now be described in more detail with reference to the accompanying drawings, in which

Fig. 1 is a perspective view and shows a heart with
25 two schematically indicated bypasses of coronary vessels each having a blocking,

Fig. 2 is a perspective view and shows one embodiment of a device according to the invention, as well as parts preferably associated therewith,

30 Figs 3 and 4 are perspective views for explaining the method of mounting the embodiment of an inventive device as shown in Fig. 2,

Fig. 5 is a perspective view of the inventive sleeve with an end portion expanded into an annular flange,

35 Figs 6a-c illustrate schematically the procedure when forming a flange on the inventive sleeve when this is enclosed by a vessel, and

Fig 7 is a perspective view of an alternative embodiment of the sleeve in Fig. 5.

The heart 1 shown in Fig. 1 has two coronary vessels 2, 3 each having a blocking 4, 5 in the form of a stenosis or an occlusion. Fig. 1 illustrates schematically how these blockings are bypassed by means of two vessels 6, 7 which can be taken from the patient himself. More specifically, one end of the vessel 6 is connected after the blocking 4, seen in the normal direction of flow in the vessel 2, and its other end is connected to the aorta 8, such that a sufficient quantity of oxygen-rich blood will be supplied to the already blocked coronary vessel 2 after the blocking 4 therein. The same applies to the vessel 3.

For effecting the connection of the vessel 6 to the coronary vessel 2, a branching device according to International Patent Application No. PCT/SE97/00804 can be used.

The connecting device according to the present invention concerns the connection of the other end 9, 10 of the vessel 6 or 7 to a vessel, e.g. the aorta 8, which thus should give a sufficient flow of blood to provide the coronary vessel 2, 3 after the blocked point 4, 5 with a sufficient supply of oxygen.

As shown in Fig. 2, the connecting device according to the invention comprises a sleeve 11 of a metal or plastic that is not rejected by body tissue. The sleeve 11 comprises an end portion 12 having a plurality of axial slots 13 and axially directed, intermediate ribs 14. Except for the end portion 12, the sleeve 11 is relatively rigid. The ribs 14 of the end portion 12 are also relatively rigid, but flexible outwards from their axial direction in Fig. 2 to a radial direction, as is best seen in Fig. 5. In the outwardly-flexed state, the ribs 14 form an annular radial end flange 15, as is also best seen in Fig. 5.

An alternative to the sleeve 11 in Fig. 5 is shown in Fig. 7. Instead of having the slots 13 and the ribs 14, the sleeve 11' in Fig. 7 is, at least at its end 12', made of a net-like flexible material, e.g. of stent type, so as to give the flange 15' of the sleeve 11' the appearance which is schematically shown in Fig. 7.

The connecting device further utilises a balloon 16, a locking ring 17 and a locking sleeve 18. Fig. 2 also shows part of the first blood vessel 6 adjacent to the end 9 thereof. More precisely, the blood vessel 6 is shown in the form it gets after being passed, end 9 first, through the sleeve 11 in the direction of the end portion 12 of the sleeve and subsequently has been folded back with its outer part over the sleeve 11.

The balloon 16 is made of an elastic material, but has an inlet tube 19 which is essentially nonelastic. The inlet tube 19 is adapted to be passed through the vessel 6, for instance after the vessel 6 has been arranged on the sleeve 11 in the manner described above. The balloon 20 may also comprise an essentially nonelastic portion 20 adjacent to the inlet tube 19 for a purpose that will be described below.

The locking ring 17 is an essentially planar ring having a plurality of axially directed pins 21, which project in the same direction from one flat side of the ring. Each pin 21 has one or more barbs 22, which ensure that the pin 21 remains once it has been passed through a material, in this case the vessel 6 and the end flange 15, as will be described in more detail below.

The locking sleeve 18 serves to safely retain on the sleeve 11 that part of the vessel 6 which has been folded back over the sleeve 11 and past the end portion 12. More specifically, the locking sleeve 18 is of such a design that it can be opened and be moved laterally over that part of the vessel 6 which has been folded back over the sleeve 11, and then be clamped, such that the interiorly of the locking sleeve 18 positioned part of the

vessel 6 is locked against the sleeve 11. Alternatively, the locking sleeve 18 can be integrally formed with the locking ring 17.

A method for connecting the vessel 6 to the vessel 8
5 by means of an inventive device will be described below
with reference to Figs 3 and 4.

The end 9 of the vessel 6 is first passed through
the sleeve 11 and folded back over the end portion 12 and
somewhat past this. The folded-back part of the vessel 6
10 is fixed on the sleeve 11 by means of the locking sleeve
18. The inlet tube 19 of the balloon 16 is moved through
the vessel 6, and the locking ring 17 is moved inwards
over the vessel 6 from the end thereof which is opposite
to the balloon 16.

15 After an opening has been made in the wall of the
vessel 8, the sleeve 11 with the vessel 6 pulled over and
locked by means of the locking ring 18 and with the bal-
loon 16 positioned within the sleeve 11 is moved so far
into the vessel 8 that the end portion 12 is positioned
20 completely inside the vessel 8. The balloon 16 is then
inflated via its inlet tube 19, the balloon 16 being in
such a position that the ribs 14 are bent outwards from
their axial direction to a more or less radial direction.
This deformation of the end portion 12 is permanent, and
25 thus the end flange 15 is formed. The fact that the inlet
tube 19 is not elastic makes it easy for the balloon 16
to affect the ribs 14 in the correct manner for the de-
sired outwards bending thereof. The desired shape of a
collar 23 formed from the vessel 6 around the end flange
30 15, i.e. the shape of the end flange 15, can be addi-
tionally guaranteed by the balloon portion 20 adjacent to
the inlet pipe 19 also being formed essentially nonelas-
tic.

When inflating the balloon 16, the shape of the
35 sleeve 11 changes from the shape shown in Fig. 3 to the
one in Fig. 4 (and also Fig. 5).

The change of the shape is shown in more detail in Figs 6a-c, where the sleeve 11 and the first vessel 6 are shown in a longitudinal cross-section, but where the balloon 16 is not included for the sake of clarity.

5 Fig. 6a shows the starting position, where the first vessel 6 is passed through the sleeve 11 and is folded back practically to the end of the sleeve 11 opposite the end 12, and where the locking ring 18 fixes the folded-back part of the first vessel 6 adjacent to the former 10 end.

Fig. 6b shows the position after the expansion of the end portion 12 of the sleeve 11 has begun. The first vessel 6 will, on the inside of the sleeve 11, essentially abut on the inside of the end portion 12, while on 15 the outside of the sleeve 11 it will extend essentially straight between the locking ring 18 and the free end of the end portion 12. Since this free end is not fixed relative to the first vessel 6, a relative movement will be possible, which is a requirement to enable expansion of 20 the first vessel 6 without being damaged to a considerable extent.

Fig. 6c shows the final position of the expansion of the end portion 12 of the sleeve 11. Also in this case, the first vessel 6 follows the inside of the end portion 25 12 but does not enter the angle between the sleeve 11 and the expanded end portion 12 on the outside of the sleeve 11. This clearance between the vessel 6 and the outside of the sleeve 11 adjacent to the expanded end portion is advantageous for the necessary seal against the second 30 vessel 8 since a pressure will thus be exerted on the inside of the edge of the opening formed in the vessel 8.

For the final fixing of the vessel 6 to the vessel 8, the locking ring 17 is moved down on the outside of the sleeve 11 towards the end flange 15, while the pins 35 21 penetrate at least the wall of the vessel 8 and the wall of that part of the vessel 6 which is folded back over the end portion 12 and forms one layer of the col-

lar 23. Because of the barbs 22, the desired locking is achieved. The pins 21 can advantageously also be made to penetrate the end flange 15 and the other layer of the collar 23 and outwards into contact with the balloon 16,
5 which, however, is so yieldable as not to be punctured by the pins 21.

Once the vessel 6 is safely connected to the vessel 8, the pressure in the balloon 16 can finally be relieved, thereby making it possible to pull out the balloon
10 through the vessel 6 by means of the inlet tube 19.

The expert realises that several modifications of the above-described embodiment of a connecting device are conceivable within the scope of the invention as defined in the appended claims. For example, the fan shape which
15 the ribs 14 of the end flange 15 have according to Fig. 5 can also be achieved without the slots 13 by folding the material of the end portion 12 like a fan.

CLAIMS

1. A device for connecting the end of a first blood
5 vessel (6) to the side of a second blood vessel (8),
which preferably has a greater diameter than the first
blood vessel, characterised by a sleeve (11,
11') whose one end portion (12, 12') is expandable for
the forming of an annular end flange (15, 15'), which is
10 adapted to be enclosed on both sides by said end of the
first blood vessel (6) for forming a collar (23) for
connecting the second blood vessel (8).

2. A device as claimed in claim 1, characterised by a balloon (16), which is arranged adjacent to the expandable end portion (12, 12') and is
15 adapted to expand the end portion and form the collar
(23) during inflation of the balloon.

3. A device as claimed in claim 2, characterised in that the balloon (16) has an inlet tube
20 (19) of an essentially nonelastic material.

4. A device as claimed in claim 3, characterised in that the balloon (16) has an essentially nonelastic portion (20), which abuts on the inlet tube
(19) and in extended state has the shape which is desired
25 for the collar (23).

5. A device as claimed in any one of claims 1-4,
characterised in that the end portion (12,
12') of the sleeve (11, 11') is made of a permanently
deformable material.

30 6. A device as claimed in any one of claims 1-5,
characterised by a locking ring (17) having
a greater inner diameter than the outer diameter of the
sleeve (11, 11') and having axially directed fixing means
(21), said locking means being adapted to fix the collar
35 (23) to the inside of the wall of the second blood vessel
(8).

10

7. A device as claimed in claim 6, characterised in that the fixing means (21) comprise pins provided with barbs (22).

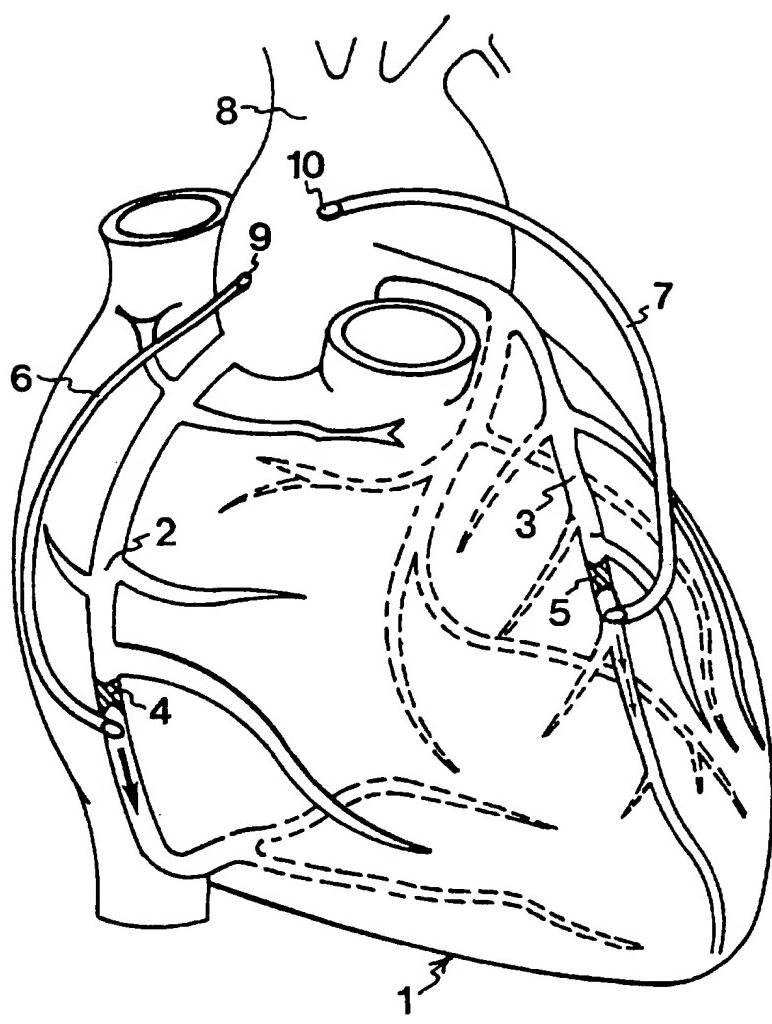
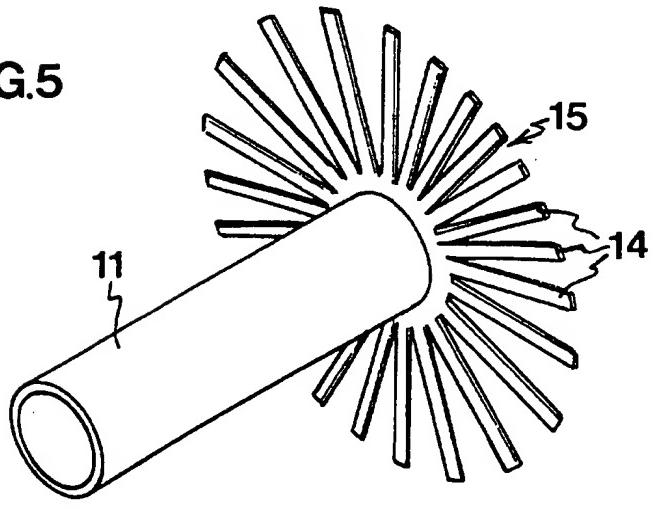
8. A device as claimed in any one of claims 1-7, 5 characterised by a clamping means (18), which is adapted to fix part of the first blood vessel (6) to the outside of the sleeve (11, 11').

9. A device as claimed in any one of claims 1-8, 10 characterised in that the expandable end portion (12') of the sleeve (11') is made of a net-like material.

10. A device as claimed in claim 9, characterised in that the sleeve (11, 11') is made of a metallic material or some other flexible material.

15 11. A device as claimed in any one of claims 1-8, characterised in that the expandable end portion (12, 12') of the sleeve (11, 11') is outwardly foldable in the form of a fan.

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FIG.1**FIG.5**

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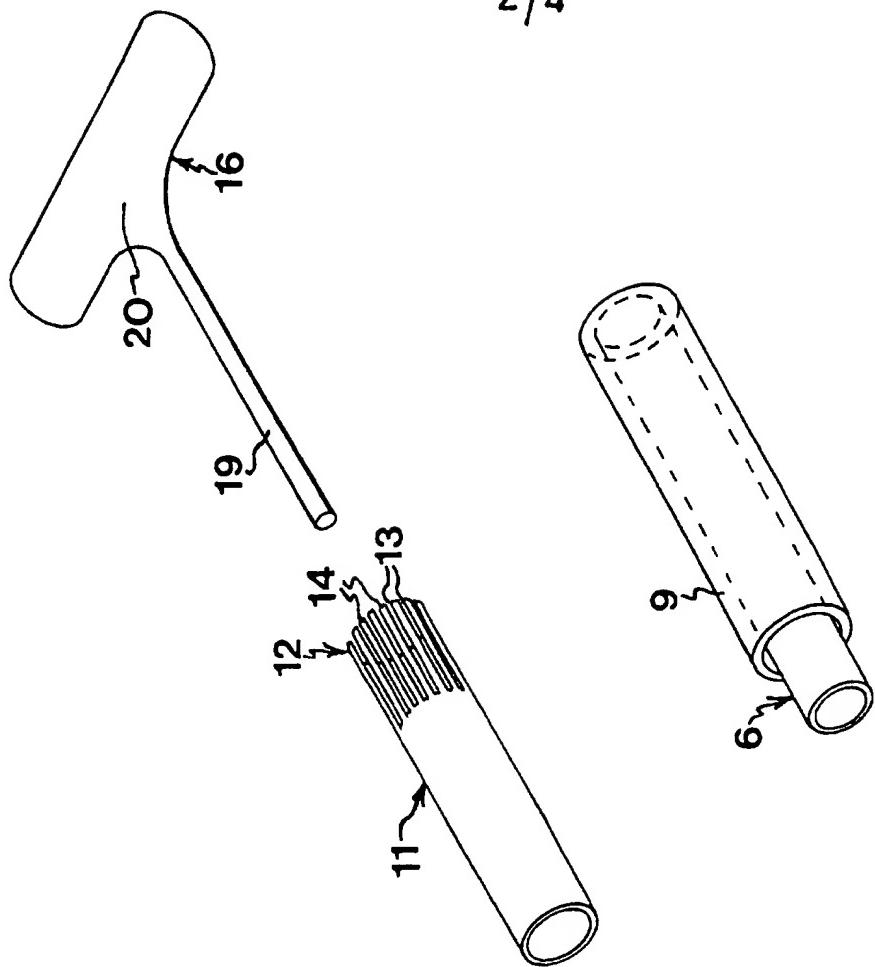


FIG.2

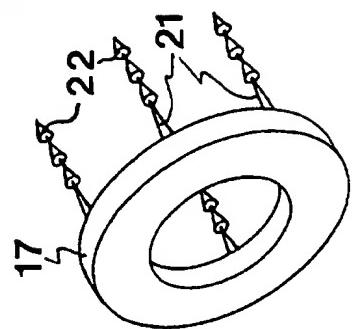
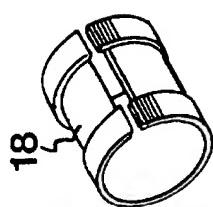
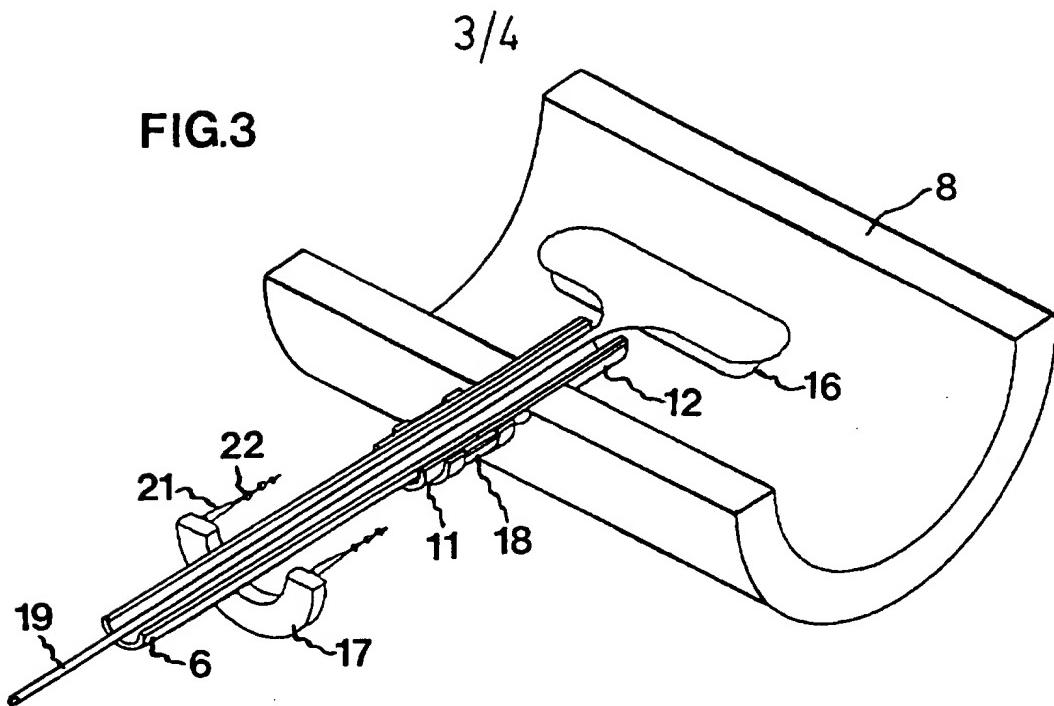
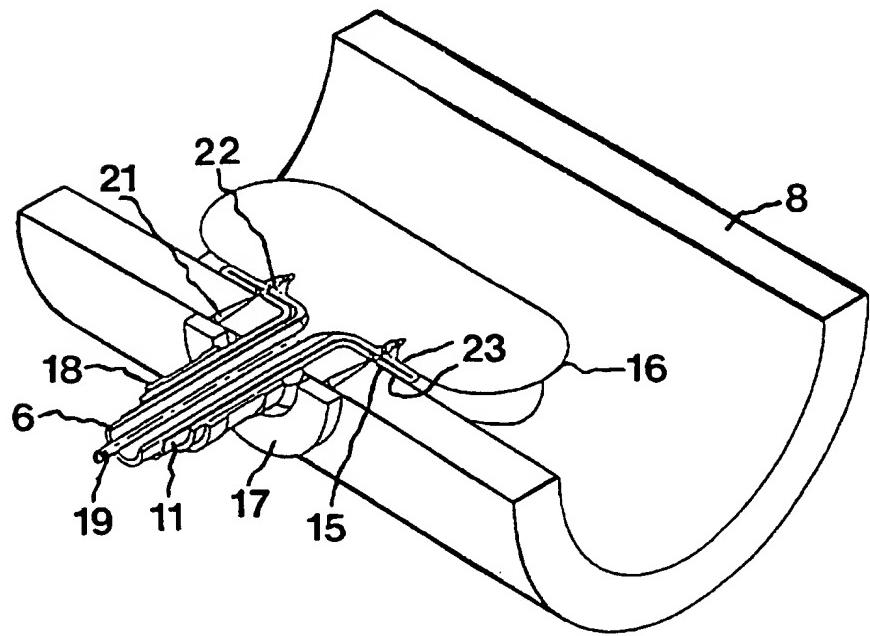
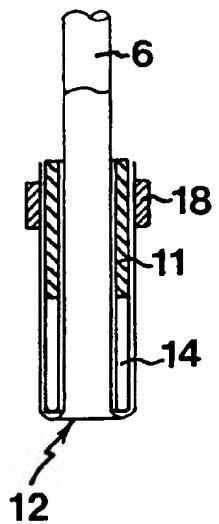
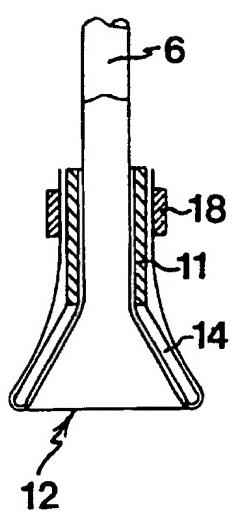
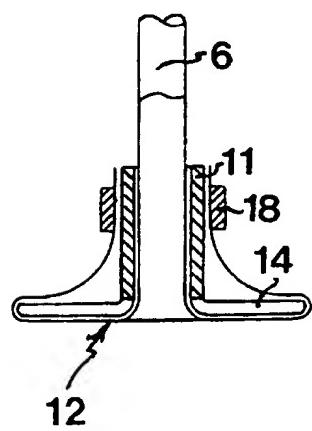
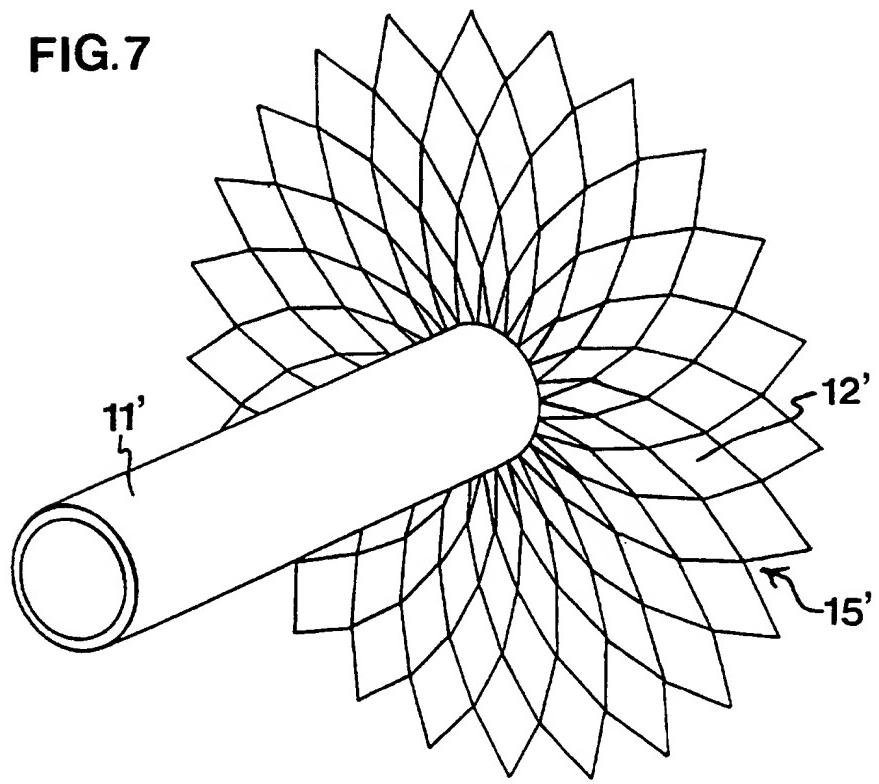


FIG.3**FIG.4**

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FIG.6a**FIG.6b****FIG.6c****FIG.7**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 97/01309

A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A61B 17/11 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC6: A61B, A61F Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2453056 A (W.E. ZACK), 2 November 1948 (02.11.48), column 2, line 24 - column 3, line 50 --	1
A	US 4787386 A (D.J. WALSH ET AL.), 29 November 1988 (29.11.88), column 9, line 34 - line 51, figure 18 --	1
A	WO 9300868 A1 (E.R. OWEN), 21 January 1993 (21.01.93), page 3, line 20 - page 5, line 20, figures 4-6 --	1
A	WO 9517128 A1 (OTICON A/S), 29 June 1995 (29.06.95), page 9, line 24 - page 12 -- -----	1-4
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search	Date of mailing of the international search report	
30 October 1997	18 - 11 - 1997	
Name and mailing address of the ISA Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. + 46 8 666 02 86	Authorized officer Anette Hall Telephone No. + 46 8 782 25 00	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/01309

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 2
because they relate to subject matter not required to be searched by this Authority, namely:
see next sheet!
2. Claims Nos.: 1
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see next sheet!
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/01309

1. claim 2

A method of treatment of the human or animal body by surgery (Article 17(2)(a) and Rule 39).

A claim is not allowable if it includes even one feature defining a physical activity or action which constitutes a method for treatment of the human body by surgery.

The characterising portion of claim 2 is directed to the use of an anastomotic instrument.

2. claim 1

The search for documents relevant to claim 1 was incomplete. It is unclear if the device is an anastomotic instrument or an anastomotic fitting. When interpreted in light of claims 3 and 4 one can assume that it is an anastomotic instrument. When interpreted in light of claims 5-11 one can assume that it is an anastomotic fitting.

The search for documents relevant to claim 1 has only covered an anastomotic fitting as stated in the description.

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/10/97

International application No.	
PCT/SE 97/01309	

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		NO 962633 A	09/08/96	
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